NFPA
The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

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Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

[Docket No. 94P-0036] Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Reopening of the Comment Period
67 Federal Register 69171, November 15, 2002

Dear Sir or Madam:

The National Food Processors Association (NFPA) submits the following comments on the docket referenced above.

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NFPA is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

NFPA previously filed comments on this docket on April 17, 2000, at which time we provided our perspectives on the presentation of *trans* fat information on the nutrition label. NFPA also filed comments on January 19, 2001, regarding nutrient content claims and health claims related to *trans* fat. NFPA appreciates the opportunity to provide additional perspective on this important matter. NFPA's comments all relate to the issue of the "*trans* fat Daily Value footnote" that the Food and Drug Administration (FDA) has put forward in its proposed rule and reopening of the comment period of November 15, 2002.

WASHINGTON, DC
DUBLIN, CA
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94P-0036 C2282

NFPA **strongly opposes** the proposed footnote "Intake of *trans* fat should be as low as possible" and the associated reference mark that would appear in the percent Daily Value column of the nutrition label. NFPA recommends that FDA should not proceed with a final rule that includes the proposed footnote or the associated reference mark.

Summary of Comments:

- The proposed *trans* fat Daily Value footnote is inherently misleading in that it is inconsistent with science, takes the recommendations from the Institute of Medicine's (IOM) Dietary Reference Intakes (DRI) macronutrient report out of context, and undermines federal dietary recommendations that suggest a diet moderate in total fat, and low in saturated fat, *trans* fat, and cholesterol.
- In light of the IOM's Food and Nutrition Board (FNB) study underway regarding uses of DRIs in nutrition labeling, FDA's proposal to add the *trans* fat Daily Value footnote and reference in the percent Daily Value column is premature.
- The proposed *trans* fat Daily Value footnote constitutes an unjustified warning statement on the labels of foods that contain *trans* fat, and does not conform with the limitations placed on FDA authority under the First Amendment. The government must satisfy a significant burden of proof establishing its legal authority to impose any particular restriction on the freedom of expression in the content of commercial speech before any such restriction can be implemented as a matter of law. As the proposed *trans* fat Daily Value footnote is inherently misleading, FDA cannot establish its authority to impose this requirement under the applicable First Amendment standard.
- The proposed *trans* fat Daily Value footnote renders invalid FDA's Preliminary Economic Impact Analysis of the original *trans* fat labeling proposed rule.
- The 30-day comment period is inadequate to address this issue.
- FDA must address several technical points related to this proposal.

NFPA's rationale for this position follows.

I. NFPA strongly opposes the proposed footnote "Intake of *trans* fat should be as low as possible" and the associated reference mark that would appear in the percent Daily Value column of the nutrition label.

A. The Proposed *Trans* Fat Daily Value Footnote is Inherently Misleading in that it is Inconsistent with Science and Takes the IOM DRI Recommendation Out of Context.

The FDA proposal bases its decision to require a *trans* fat Daily Value footnote associated with the percent Daily Value solely on the recommendation from the Institute of Medicine's (IOM) report on Dietary Reference Intakes (DRIs) for macronutrients.[1] However, in the November 15, 2002, proposal, FDA also makes note of dietary recommendations contained in the *Dietary Guidelines for Americans* [2] and the National Cholesterol Education Program (NCEP) Adult Treatment Panel III report[3]. NFPA believes that, taken together, the recommendations in these three reports added to this docket support the need for reducing dietary intake of *trans* fatty acids, and are consistent. However, they lead to a conclusion different from FDA's proposed *trans* fat Daily Value footnote, and different from what the footnote reflects or conveys.

First, NFPA questions whether the weight of the scientific evidence in the IOM report is sufficient to support the *trans* fat Daily Value footnote as proposed, and to override dietary recommendations from the *Dietary Guidelines for Americans* and NCEP. We refer FDA to detailed comments related to the scientific soundness of *trans* fat recommendations in the IOM report submitted to this docket by the International Life Sciences Institute North America (ILSI N.A.).

NFPA believes it is significant that the IOM Committee did not establish a DRI for trans fatty acids because "there are no known requirements for trans fatty acids...for specific body functions,"[4] A Tolerable Upper Intake Level for *trans* fat was not set despite the relationship between intake of trans fatty acids and coronary heart disease risk (increases

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[1] IOM (Institute of Medicine). 2002 (prepublication copy; 2 volumes). Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. Report of the Panel on Macronutrients, Panel on the Definition of Dietary fiber, Subcommittee on Upper Reference Levels of Nutrients, Subcommittee on Interpretation and Uses of Dietary Reference Intakes, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board. Washington, DC: The National Academies Press. Note that page numbering is as it appears in the prepublication copy.

[2] U.S. Department of Agriculture and U.S. Department of Health and Human Services. 2000. Nutrition and Your Health: Dietary Guidelines for Americans, 2000. USDA Home and Garden Bulletin No. 232. Washington, DC: U.S. Government Printing Office. Also accessible via http://www.health.gov/dietaryguidelines/dga2000/document/frontcover.htm.

[3] NCEP (National Cholesterol Education Program). 2002. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). Final Report. National Heart, Lung, and Blood Institute, National Institutes of Health. Accessed at http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3_rpt.htm.

[4] IOM, page 8-23.

LDL [low-density lipoprotein] cholesterol), "[b]ecause trans fatty acids are unavoidable in ordinary, non-vegan diets, consuming 0 percent of energy would require significant changes in patterns of dietary intake," and such a dietary pattern "may result in inadequate intakes of protein and micronutrients," and "unknown and unquantifiable health risks."[5] The IOM Committee concludes their discussion by stating, "It is possible to consume a diet low in trans fatty acids by following the dietary guidance provided in Chapter 11."[6] Given these perspectives, adopting the proposed *trans* fat Daily Value footnote runs counter to the views in the IOM report and will mislead consumers, as it increases the likelihood that dietary patterns would be distorted.

Chapter 11 of the IOM report, titled "Macronutrients and Healthful Diets," provides additional information critical to understanding the context of macronutrient distribution in the diet. The chapter provides "guidance on minimizing intakes of these three nutrients [saturated fatty acids, *trans* fatty acids, and cholesterol] while consuming a nutritionally adequate diet."[7] For *trans* fatty acids, the chapter urges consumers to make wise food choices to reduce intake of *trans* fatty acids. Chapter 11 further states, "There are no known risks of chronic disease from consuming low intakes of saturated fatty acids, *trans* fatty acids, or cholesterol."[8] Thus, the proposed *trans* fat Daily Value footnote lacks full context of the IOM report and other federal dietary recommendations.

Second, the proposed *trans* fat Daily Value footnote is more prescriptive than the recommendations in the year 2000 edition of *Dietary Guidelines for Americans.* The Dietary Guidelines categorize recommendations into three groups: Aim for Fitness, Build a Healthy Base, and Choose Sensibly. The category "Choose Sensibly," contains the guideline for dietary fat and cholesterol, "Choose a diet that is low in saturated fat and cholesterol and moderate in total fat."[9] Its discussion includes guidance to reduce dietary consumption of *trans* fatty acids. In addition, the Dietary Guidelines document states, "...guidelines help you make sensible choices that promote health and reduce the risk of certain chronic diseases. You can enjoy all foods as part of a healthy diet as long as you don't overdo it on fat (especially saturated fat), sugars, salt, and alcohol. Read labels to identify foods that are higher in saturated fats, sugars and salt (sodium)."[10] The Dietary Guidelines recommend that consumers aim for a total fat intake of no more than 30 percent of calories, keep saturated fat at less than 10 percent of calories, and limit the use of hard margarines and partially hydrogenated shortening, but does not recommend that consumption of *trans* fat be "as low as possible".[11]

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[5] IOM, page 8-66.
[6] IOM, page 8-66.
[7] IOM, page 11-2.
[8] IOM, page 11-46.
[9] DG 2000, pages 28-31.
[10] DG 2000, page 3.
[11] DG 2000, pages 28- 31.

Third, the dietary recommendations contained in the NCEP report indicate that *trans* fatty acids is not a major constituent of dietary fat intake. The NCEP report states that *trans* fatty acid intake should be kept low, but acknowledges that the mean level of *trans* fatty acid intake is about 2.6 percent of total energy[12] (approx. 6 g in a 2000 kcal/d diet; range of 1.6 g/d [10th percentile for women 20 – 49] to 11.6 g/d [90th percentile for men 20 – 49] [13]). Thus, average intake of *trans* fatty acids constitutes only a few grams per day. In the context of the NCEP dietary recommendations, total fat should be 25 to 35 percent of kcal/d, saturated fat should be less than 7 percent of kcal/d, and dietary cholesterol less than 200 mg/d. These recommendations illustrate advances in scientific knowledge about diet and coronary heart disease risk since Daily Values were established in 1993, and realistic dietary goals similar to the dietary recommendations in Chapter 11 of the IOM report (Acceptable Macronutrient Distribution Ranges and cautions about imbalance or severe restriction of macronutrients) and the Dietary Guidelines (moderate fat intake and reduce saturated fat and cholesterol). These recommendations thus support NFPA's position that the proposed *trans* fat Daily Value footnote is misleading to consumers and inconsistent with the scientific principles and dietary recommendations upon which this proposed rule is based.

Finally, in the preamble to the 1993 final rule for nutrient content claims,[14] at comments 11 and 12, FDA stated, "the agency believes that 'there are no generally recognized levels at which nutrients, such as fat, saturated fat, cholesterol, or sodium in an individual food will pose an increased risk of disease.' The disclosure levels are not tied to concerns about consuming the individual food but to concerns that claims can mislead consumers about the significance of the food in the total daily diet, and that rather than facilitating compliance with dietary guidelines, such claims could make compliance with such guidelines more difficult if certain relevant information is not brought to the consumer's attention."[15] While these comments relate to nutrient content claim disclosures, NFPA believes that the Agency is correct in rejecting the need for warnings to consumers about nutrient content. Thus, FDA should not adopt the proposed *trans* fat Daily Value footnote because it is a warning. Furthermore, we believe the *trans* fat Daily Value footnote will cause consumers to draw a false conclusion and be misled into pursuing inappropriate and unintended dietary behaviors.

NFPA believes that the proposed *trans* fat Daily Value footnote statement, "Intake of *trans* fat should be as low as possible," will cause consumers to substitute foods with higher levels of saturated fatty acids, total fat, or other nutrients for foods that have any amount of *trans* fatty acids. In other words, the proposed *trans* fat Daily Value footnote will readily impair extensive public and private efforts to provide consumers guidance on

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[12] NCEP, page V-4.
[13] Data from original source. Allison, DB et al. 1999. Estimated intakes of *trans* fatty and other fatty acids in the US population. J Am Diet Assoc 99(2):166-174.
[14] Food Labeling: Nutrient content claims, general principles, petitions, definition of terms; Definitions of nutrient content claims for the fat, fatty acid, and cholesterol content of food. 58 FR 2302, January 6, 1993.
[15] 58 FR 2302 at 2307.

fat and components through the Dietary Guidelines and the food consumption recommendations of the Food Guide Pyramid to assist in making overall dietary choices. This entire approach, therefore, is inconsistent with the federal dietary recommendations that suggest a diet moderate in total fat, and low in saturated fat, *trans* fat, and cholesterol.

This proposed dramatic change in nutrition labeling has not been evaluated by qualitative or quantitative consumer research, as was done with development of the Nutrition Facts panel following passage of the Nutrition Education and Labeling Act (NLEA). NFPA believes that this is a critical evaluation incumbent upon FDA to conduct. Participants in a 1999 Ceres® Forum workshop, "Fat in the American Diet: The Science and the Policy," provided insight into cautions about differing approaches for labeling of *trans* fatty acids.[16] Participants from FDA, academia, and industry expressed views about dietary guidance and labeling issues related to dietary fat and fatty acids. At the workshop, FDA staff indicated that, at that time, public awareness and knowledge of *trans* fatty acids was only approximately 20 percent, and that, citing previous FDA consumer studies, expressed concern over the difficulty to teach the intricacies of fatty acid chemistry.[17] Academic discussants expressed concern that *trans* fatty acids information provided on the Nutrition Facts panel would lead consumers to focus only on *trans* fats and forget about saturated fat.[18] This would likely be the case if the Agency proceeds with its proposal.

NFPA believes that the FDA proposed *trans* fat Daily Value footnote will mislead consumers to consider this dietary component out of balance with overall dietary recommendations in general, and with dietary fat components in particular. It is likely that the *trans* fat Daily Value footnote would cause consumers to prefer foods containing saturated fats, since such foods would bear no alarmist footnote. Consumers would be likely to avoid *trans* fats at all costs. This behavior will distort dietary intakes in unhealthful ways, prompting the very dietary behavior that the IOM Committee recommended not be followed. Thus, the net effect of the proposed *trans* fat Daily Value footnote is that it is likely to be harmful. FDA's principal requirement must remain to first "do no harm."

Given the future evolution of nutrition labeling requirements, NFPA believes that it is both premature and inappropriate to consider these dramatic changes separate from other Nutrition Facts panel components that will be evaluated and revised over the next several years.

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[16] Center for Food and Nutrition Policy. 1999. Fat in the American Diet: The Science and the Policy. Proceedings from a Ceres® Forum workshop, W. Sansalone, ed. Alexandria, VA: Virginia Tech Center for Food and Nutrition Policy.

[17] Ceres Forum remarks by Alan Levy, PhD, FDA consumer study scientist. Pp. 63-65, 71.

[18] Ceres Forum remarks by Penny Kris-Etherton, PhD, RD, Pennsylvania State University. Pp. 70-71.

B. In light of the study underway regarding uses of DRIs in nutrition labeling, FDA's proposal to add the *trans* fat footnote and reference in the percent Daily Value column is premature.

Within the past two years, FDA has signaled that it will review and revise, if necessary, Daily Values for nutrition labeling following completion of the DRI project by the Food and Nutrition Board (FNB), of the Institute of Medicine (IOM), National Academy of Sciences (NAS). Under contract by FDA, the U.S. Department of Agriculture (USDA), and Health Canada, the IOM has a study underway examining the uses of DRIs in nutrition labeling. Quoting the charge to the Committee conducting the study, Use of Dietary Reference Intakes in Nutrition Labeling, the panel—

> "will assess the objectives, rationale, and recommendations for the methodology to select reference values for labeling the nutritive value of foods based on the Dietary Reference Intakes (DRIs).... The study will identify general guiding principles for use in setting reference values for nutrients on the food label, recognizing that there may be modifications of the approach based on special situations or physiological needs related to each nutrient; these modifications will be outlined and the rationale for them described. Consideration will be given to the use of food label reference values to compare different food products and to determine the relative contributions of foods to an overall diet; the scientific basis for principles to be used to guide the selection of values for different nutrients, possibly using examples from various classes of nutrients; whether a single set of standard values or different sets for various age and gender groups are needed; and how the reference values should be expressed."

The study is underway and active, and the Committee conducting the study has held two public workshops, May and November 2002. The FNB Committee is expected to conclude its work in mid-2003, and is scheduled to issue a report in September 2003.

This FNB Committee is expected to develop principles for applying the recommendations from the DRI reports to nutrition labeling, with an expected focus on Daily Values. As several nutrients in the DRI reports have no intake recommendations, or few intake recommendations, in addition to quantitative recommendations, NFPA believes it is clear that **FDA should wait** to examine the Daily Value concept for all nutrients at once, and not address *trans* fat out of context, setting an unfortunate precedent with the footnote related to *trans* fat and the percent Daily Value.

Given the work of the FNB Committee, NFPA and its members reasonably anticipate that FDA is likely to propose rules governing presentation of Daily Values on nutrition labels sooner than later. This future proposal is likely to result in changes to the majority of nutrition labels. Coupled with the current proposal on the *trans* fat Daily Value footnote, it is clear that foods containing *trans* fat are likely to undergo two revisions with respect to the Daily Value information within approximately five years. This prospect of

sequential required label changes is not acceptable to NFPA and its members. It is a far more efficient use of regulatory resources, and a lower cost approach for food processors, for FDA to make all revisions to Daily Value scheme once. Most importantly, such a coordinated approach also will be less confusing to consumers.

NFPA appreciates the challenge that FDA faces in developing a scheme for *trans* fat nutrition labeling that presents label information in the context of the daily diet. However, for about ten years, other nutrients required or permitted to be declared on the nutrition label (e.g., monounsaturated fat, polyunsaturated fat, other carbohydrate, sugars) have been presented without a Daily Value to establish that context.[19] NFPA believes that consumers are not misled by the presentation of factual information concerning the quantities per serving of these nutrients. In light of the pending IOM study and FDA's future examination of Daily Values, NFPA strongly urges that FDA not establish a footnote of percent Daily Value in reference to *trans* fatty acids, and not disclose information to consumers that may be misleading or changed in the near future.

C. The Proposed *Trans* Fat Daily Value Footnote Constitutes an Unjustified Warning Statement on the Labels of Foods That Contain *Trans* Fat, and Does Not Conform to Constitutional Requirements.

In the current proposed rule, FDA has provided no evidence establishing that the Agency has legal authority to require the proposed footnote for *trans* fat nutrition labeling, as is required by the First Amendment. The First Amendment protects both the right to speak and the right to refrain from speaking. These protections set firm boundaries on the government's authority to restrict the freedom of expression, either by prohibiting speech or by compelling speech. NFPA believes the government has insufficient authority to regulate the content of commercial speech through compelled speech like the proposed *trans* fat Daily Value footnote. NFPA believes that FDA has failed to carry its burden of proof under the First Amendment.

C. 1. The Government Must Satisfy a Significant Burden Before It Can Mandate Commercial Speech.

The First Amendment guarantees "both the right to speak freely and the right to refrain from speaking at all." *Wooley v. Maynard*, 430 U.S. 705, 714 (1977). *See also National Comm'n on Egg Nutrition v. F.T.C.*, 570 F.2d 157, 160 (7th Cir. 1977) (requirement that egg producers state that many medical experts believe that increased cholesterol may increase heart disease violates First Amendment); *United States v. Nat'l Soc'y of Prof'l Eng'rs*, 555 F.2d 978 (D.C. Cir. 1977) (requirement that engineering society state that it

[19] Declaration of the Daily Value for protein is optional, except for certain types of foods and unless protein claims are made.

does not consider competitive fee bidding to be unethical violates First Amendment), *aff'd*, 435 U.S. 679 (1978).

Thus, the First Amendment is as concerned with limiting government power to compel speech as to ban speech:

> "The essential thrust of the First Amendment is to prohibit improper restraints on the *voluntary* public expression of ideas; it shields the man who wants to speak or publish when others wish him to be quiet. There is necessarily, and within suitably defined areas, a concomitant freedom *not* to speak publicly, one which serves the same ultimate end as freedom of speech in its affirmative aspect."

Harper & Row, Publishers, Inc. v. Nation Enter., 471 U.S. 539, 559 (1985) (emphasis in original) (citation omitted). *See also Riley v. Nat'l Fed'n of The Blind*, 487 U.S. 781, 795 (1988) ("Mandating speech that a speaker would not otherwise make necessarily alters the content of the speech.").

The First Amendment deprives the government of authority to restrict or dictate the content of commercial speech, including food labeling, except where the government first is able to establish that the particular restriction satisfies the requirements articulated by the Supreme Court in *Central Hudson Gas & Electric Corp. v. Public Service Commission,* 447 U.S. 557, 566 (1980) (the "*Central Hudson*" test). Under the *Central Hudson* test, the government is prohibited from restricting or mandating the content of commercial expression except where such restrictions directly advance a "substantial" government interest, and are designed in a manner that are no more extensive than necessary to advance the interest articulated by the government. *Id.*[20]

The *Central Hudson* test amounts to a means-to-ends "efficacy" test, and permits the government to rely on commercial speech restrictions to accomplish public policy objectives only in those narrow circumstances in which the restrictions are effective in mitigating genuine harms to the public that are established based on evidence. The Supreme Court has made clear that the government's burden is not satisfied by mere speculation or conjecture. No restriction on commercial speech can be sustained under this test unless the government "demonstrate[s] that the harms it recites are real and that [the speech restriction] will alleviate them to a material degree." *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993).

In the seminal food labeling decision *International Dairy Foods Association v. Amestoy*, 92 F.3d 67 (2d Cir. 1996), a case brought on behalf of International Dairy Foods Association, National Food Processors Association, and the Grocery Manufacturers of America, the court held that the State of Vermont's asserted interests in responding to

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[20] Several justices have expressed dissatisfaction with the *Central Hudson* test—feeling that it is insufficiently protective of free speech—but for now it remains governing law. *See Thompson v. W. States Med. Ctr.*, 122 S. Ct. 1497, 1504 (2002)(commenting on the dissatisfaction).

"strong consumer interest and the public's right to know" were insufficient "to justify compromising protected constitutional rights" through the mandatory labeling of milk products derived from cows treated with genetically engineered bovine somatotropin (BST). 92 F.3d at 73.

As a general matter, the Supreme Court has recognized that prevention of consumer deception and public health protection are public policy objectives that may constitute substantial governmental interests. The Supreme Court has made clear that the government has a substantial interest in "ensuring the accuracy of commercial information in the marketplace." *Edenfield v. Fane*, 507 U.S. 761, 769 (1993). In addition, the Court has recognized that the government has a substantial interest in "promoting the health, safety, and welfare of its citizens." *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 485 (1995).

Nonetheless, even where the governmental interest is established to be substantial, the speech restriction cannot be sustained unless the restriction "directly advances" the government interest and is "not more extensive than is necessary to serve that interest." *Thompson v. W. States Med. Ctr.*, 122 S. Ct. 1497, 1504 (2002). Speech restrictions that interfere with the dissemination of useful product information and do not directly further any substantial governmental interest are unconstitutional. *Id.* at 1508-09.

C. 2. The Inherently Misleading Nature of the Proposed *Trans* Fat Daily Value Footnote Indicates that the Government Cannot Carry its Burden of Proof under the First Amendment.

The First Amendment would not support the government in regulating commercial speech to make it misleading. The government has no authority under the First Amendment standard to compel manufacturers to put misleading speech on their labels. As we have noted, the *trans* fat Daily Value footnote, in the form proposed by FDA, is misleading because it is not substantiated by the IOM report or supported by other dietary recommendations, and is likely to lead to inappropriate and unintended dietary behaviors. In addition, the deceptive nature of the footnote is likely to encourage consumers to engage in unhealthful eating patterns by attempting to avoid *trans* fat at all costs, and thus distort dietary intake in unhealthful ways. There is no evidence that this footnote will alleviate harm, and there is much reason to believe it will cause consumer deception and have a negative effect on health.

Even if the footnote itself were factually accurate, under the First Amendment standard FDA would lack authority to require this footnote statement under the conditions proposed because it cannot be established from the evidence that the footnote is appropriately tailored to advance a substantial governmental interest.

Like the labeling at issue in *Amestoy*, the mandatory labeling of this proposed rule communicates a "warning" to consumers, suggesting that some material distinction exists between foods declaring *trans* fat, even if zero, on a separate line of the nutrition label with the proposed *trans* fat Daily Value footnote, and those foods that may note *trans* fat in a "not a significant source of . . . " footnote. The use of the *trans* fat Daily Value footnote appears to advise consumers to avoid foods with any amount of *trans* fat. Such a footnote may persuade consumers to select foods with higher levels of saturated fat, which has no Daily Value footnote warning statement. Such direction to consumers runs counter to public health protection, and would deceive consumers with respect to the actual nutritional value contributed by foods containing *trans* fat, compared to saturated fat alternatives.

FDA only provides justification based in the Federal Food, Drug and Cosmetic Act for the *trans* fat Daily Value proposal, certainly a justification that does not pass constitutional scrutiny. NFPA believes that FDA cannot carry its burden of proof under the First Amendment to compel the declaration of the proposed *trans* fat Daily Value footnote under the conditions stated by FDA.

D. The Proposed *Trans* Fat Daily Value Footnote Renders Invalid FDA's Preliminary Economic Impact Analysis of the Original *Trans* Fat Labeling Proposed Rule.

In November 1999, as part of the *trans* fat nutrition labeling proposed rule, FDA prepared an extensive Preliminary Regulatory Impact Analysis (PRIA) to discuss the estimated costs and benefits of the proposed rule. The PRIA was predicated on FDA's proposed approach to *trans* fat nutrition labeling, namely, to combine the quantity of *trans* fat per serving with saturated fat on the saturated fat line of the nutrition label, calculate the combined quantity against the 20 gram Daily Value for saturated fat and present the result of the computation in the percent Daily Value column, at the saturated fat line, and to present a factual footnote noting the quantity of *trans* fat that was included in the combination of *trans* fat and saturated fat. Key to the PRIA was FDA's assumption that many nutrition labels would not need to be changed to accommodate the proposed mode of *trans* fat nutrition labeling; the only labels requiring changes would be those for foods that contained *trans* fat in a declarable amount, at least 0.5 grams per serving.

The *trans* fat Daily Value footnote that FDA has proposed would necessitate changes to nearly all nutrition labels. Changes to the nutrition label would be necessary, either to add a separate line declaring grams of *trans* fat per serving, even if zero, along with the proposed *trans* fat Daily Value footnote, or to add *trans* fat to the nutrition label footnote "not a significant source of . . . (naming nutrients not declared)". Only in those few instances of food products labeled with a simplified format, and which make no nutrition claims or declare voluntary nutrients, and contain less than 0.5 g of *trans* fat, would *trans* fat not be required to be noted on the nutrition label.

In its November 1999 proposed rule, FDA contemplated the presentation of *trans* fat information on a separate line of the nutrition label. FDA rejected this approach. In the PRIA, FDA noted that the separate line presentation of *trans* fat information would necessitate changes to virtually all nutrition labels. FDA noted that this presentation of *trans* fat information would present higher relabeling costs with no incremental benefits.

> "If the agency were to require listing the amount of *trans* fat on a separate line in the Nutrition Facts panel, all labels would have to be changed—including those for products containing no *trans* fat. These additional labeling costs would have no additional benefits associated with them."[21]

Because the premise of the regulatory impact analysis has changed, primarily by virtue of FDA's proposal to include the *trans* fat Daily Value footnote, NFPA believes that FDA must now reanalyze the costs and benefits and present these factors for public discussion.

E. The 30-Day Comment Period is Inadequate to Address this Issue.

The proposal to use a footnote rather than a calculated percent Daily Value for *trans* fat would establish precedent for nutrition labeling. Providing merely a 30-day comment period for such an important precedent does not allow for careful deliberation of this issue. Providing only 30 days to comment on the proposal also gives short shrift to the international obligations of the United States, with respect to responsive comments from other nations. This is especially important given the pending nutrition labeling rules from Canada, the United States' major trading partner.

II. Technical Points the FDA has Ignored

FDA has overlooked several sections of rules in putting forward the *trans* fat Daily Value footnote proposal, as there are paragraphs of nutrition labeling rules that would be affected by such a proposal, yet were not discussed in the November 1999 proposed rule. The most significant of these sections of rules include:

- Definition of *trans* fat, given the differences between FDA's original proposal and the scope of the IOM/NAS DRI report (21 CFR 101.9(c)(2)).
- Order of declaration of *trans* fat with respect to other fatty acids on the nutrition label (21 CFR 101.9(c)(2))
- Provisions for simplified nutrition label format. NFPA believes that FDA must repropose this rule, as an additional required nutrient would need to be factored into the determination of qualification for this format (21 CFR 101.9(f)).

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[21] 64 FR 62746 at 62764, November 17, 1999.

- Provisions for the nutrition labeling of foods for infants and young children (21 CFR 101.9(j)(5)).
- Provisions for nutrient content claims and health claims related to *trans* fat.

NFPA believes that it is necessary for FDA to solicit comments on the effects to these sections of regulations caused by the Agency's currently proposed presentation of *trans* fat nutrition information, in order to conform with requirements of the Administrative Procedures Act.

Thank you for the opportunity to comment on this important issue. For all the reasons articulated above, NFPA **strongly opposes** the proposed footnote "Intake of *trans* fat should be as low as possible" and the associated reference mark that would appear in the percent Daily Value column of the nutrition label, and recommends that FDA not proceed with a final rule that includes the proposed footnote or the associated reference mark. We would welcome the opportunity to discuss with the Agency, at their convenience, any of the points raised herein to support our position if the Agency would find it useful.

Sincerely,

Rhona S. Applebaum

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